Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparative bioequivalence study of Loratadine 10 mg Tablet of Karen Pharma and Food Supplement Co. and Claritine® of NBAYER as reference in 24 healthy male under fasting.

Protocol summary

Study aim
This study will be performed to compare the pharmacokinetics and invivo parameters of Loratadine 10 mg Tablet formulation as a test product with Claritine 10 mg Tablet formulation as a reference product to evaluate the bioequivalence.

Design
Non blinded, randomized, crossover in vivo bioequivalence study in 24 healthy male under fasting condition. Block randomization for a treatment sequence of Test/Reference or Reference/Test will be used.

Settings and conduct
In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran) according to a prepared block randomization schedule without blinding. 16 blood samples were collected during 72 hours post intervention. A 14-day washout interval separated 2 study periods.

Participants/Inclusion and exclusion criteria
Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of the normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination; laboratory evaluations; known allergy to loratadine; history of hypertension.

Intervention groups
Intervention group 1: Loratadine 10 mg Tablet, produced by Karen is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects. Intervention group 2: Claritine 10 mg Tablet, produced by Novartis is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product. After 7-day wash-out period the intervention 1will be given to these subjects.

Main outcome variables
Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180620040164N41**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**
Update count: **0**

Registration date
2023-02-25, 1401/12/06

Registrant information

Name
Behzad Montaha Sangari
Name of organization / entity
Noor research and educational institute (Tavan)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-26, 1402/02/06

Expected recruitment end date
2023-05-10, 1402/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative bioequivalence study of Loratadine 10 mg Tablet of Karen Pharma and Food Supplement Co. and Claritine® of NBAYER as reference in 24 healthy male under fasting.

Public title
Comparative in vivo evaluation of 2 Loratadine 10 mg Tablet formulations.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range according to the accepted normal values between 18.5 and 30 (inclusive), calculated as kg/m2. Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects with normal vital signs. Subjects who agree with patient consent form.
Exclusion criteria:
Subjects with known allergy to loratadine. Had history of hypertension. Had Concurrently used enzyme modifying drugs especially erythromycin, MAO inhibitors, ketoconazole, and cimetidine. Had recent history of abdominal pain, epistaxis or sleep disturbances. Had history of any psychiatric illness, which may impair the ability to provide, written informed consent. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Consumption of enzyme modifying drugs within 30 days prior to Day 1 of this study. History of alcohol or drug abuse. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.
Age
From **20 years** old to **45 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization schedule will be generated with https://www.sealedenvelope.com/simple-randomiser/v1/lists. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each volunteer.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2023-01-24, 1401/11/04
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.235

Health conditions studied

1

Description of health condition studied
Allergic rhinitis, unspecified
ICD-10 code
J30.9
ICD-10 code description
Allergic rhinitis, unspecified

Primary outcomes

1

Description
Peak Plasma Concentration (Cmax)
Timepoint
Before intervention and then at 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48 and 72 hours post intervention in each period
Method of measurement
using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description
AUC (Area Under the Concentration-Time Curve)
Timepoint
Before intervention and then at 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 10, 12, 24, 48 & 72 hours post intervention in each period
Method of measurement
using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description
Intervention group 1: Loratadine 10 mg tablet, produced by Karen is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.
Category
Treatment - Drugs

2

Description
Intervention group 2: Loratadine 10 mg tablet produced by BAYER is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1will be given to these subjects.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hakim Farabi Clinic
Full name of responsible person
Ebrahim Siahpoosh
Street address
No. 57, Shemshad alley, Sallor city
City
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4635314588
Phone
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Email
partochem@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karen Pharma and Food Supplement Co.
Full name of responsible person
Zahra Mortazavi
Street address
No: 3, Western Nahid st. Africa Blvd.
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Province
Tehran
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۱۴۵۹۹۶۵۲۰۴
Phone
+98 21 2620 4283
Email
info@karenpharma.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karen Pharma and Food Supplement Co.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Noor Research & Development Institute
Full name of responsible person
Ali aghaei
Position
Master
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Province
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Postal code
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Email
info@tavaninstitute.ir

Person responsible for updating data

Contact
Name of organization / entity
Tavan Institute
Full name of responsible person
Ali Aghaei
Position
Master
Latest degree
Master
Other areas of specialty/work
Pharmacy
Street address
Sharif innovation station, North Habibollah, Hosseini Squ., Teymoury St., Tarasht.
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1459926609
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It's not specified yet.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available